IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMICUS THERAPEUTICS US, LLC and AMICUS THERAPEUTICS, INC., *Plaintiffs*, v. TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS, INC., *et al.* *Defendants*.	C.A. No. 1:22-cv-01461-CJB ANDA Case (Consolidated)

DEFENDANTS AUROBINDO PHARMA LTD. AND AUROBINDO PHARMA USA, INC.'S REPLY BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF ALL ASSERTED PATENTS UNDER 35 U.S.C. § 101

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Rules

Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., (collectively for identification purposes, "Aurobindo"), through their undersigned counsel, hereby submit their Reply Brief in Support of Aurobindo's Motion for Summary Judgment of Invalidity of the Asserted Patents, in accordance with Rule 56 of the Federal Rules of Civil Procedure. In support of their Motion, Aurobindo states as follows:

I. Reply to Plaintiffs' Statement of the Nature and Stage of the Proceedings

Plaintiffs waste no time trying to obfuscate the record in this case, including in their description of the letter Aurobindo submitted requesting permission to file its summary judgment motion. (*See* D.I. 230 at 1; *see also* D.I. 198 at 2.) Aurobindo's commitment to not "file" a motion for summary judgment if expert opinion was needed was intended to avoid wasting the Court's resources with a motion if a legitimate, material difference of opinion had arisen between experts. It was not intended to restrict Aurobindo from pointing to expert opinions or testimony in reply to Plaintiffs' best efforts to avoid summary judgment.

Regardless, Aurobindo respectfully submits that Plaintiffs have failed to point to any difference of opinion that bears on any issue raised by Aurobindo's Motion. Furthermore, Aurobindo maintains that none of the opinions offered by the experts are relevant either to the meaning and scope of the Asserted Claims or to whether their subject matter renders them invalid under 35 U.S.C. § 101. Finally, Aurobindo notes that it does not here cite expert opinions or testimony. Therefore, there is no question as to Aurobindo's faithful compliance with its commitments to the Court and Plaintiffs, who have failed to create a battle of the experts on any issue material to Aurobindo's position that the Asserted Claims are directed to unpatentable subject matter under § 101, best efforts notwithstanding.[1]

[1] The air of impropriety Plaintiffs' statement seems intended to raise is almost comical in view of Plaintiffs' choice to exceed the 20-page limit for briefs in this District without seeking leave of

II. Plaintiffs Have Failed to Raise a Triable Question as to Whether the Asserted Claims Are Directed to an Ineligible Concept.

One need not be terribly observant to note a pattern among the Asserted Claims. Each is directed to the very same method of treatment, though not every claim uses identical language, and not all of the Asserted Claims are related. Every time a new mutation is identified as migalastat amenable, it seems, Amicus believes it is entitled to extend its monopoly on its FDA-approved migalastat product, Galafold, even if only to a specified subgroup of patients in need of migalastat treatment.

Genetic mutations notwithstanding, the Asserted Claims are directed to methods of treating Fabry Patients in need of migalastat treatment. They are not directed to a method of selecting patients. They are not directed to a method of determining migalastat amenability. They are not directed to any assays. They merely incorporate the results of an unclaimed (in the Asserted Claims) assay that identifies specific Fabry mutations' natural reaction to migalastat. Aurobindo respectfully submits the assay results describe a natural phenomenon, and the Asserted Claims do not otherwise transform those results into a patentable invention.

Plaintiffs nowhere dispute Aurobindo's assertion that the scope of the methods claimed in the Plaintiffs' own, unrelated '011 patent (U.S. Patent No. 9,000,011; *see* Barry Decl. Ex. 5)[2], are not materially distinct from the scope of the Asserted Claims. The point of this comparison is to

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Court. *See* D.Del. L.R. 7.1.3(a)(4); *see also* L.R. 7.1.2(a) (requiring "responsive papers" to "be in the form adopted by the moving party") and (c) (detailing the contents of briefs). Aurobindo respectfully submits that Plaintiffs' separately filed Response to Aurobindo's Statement of Material Facts (*see* D.I. 231), which statement Aurobindo included within its 15-page opening brief, is improper and violates the local rules. Aurobindo hastens to note that Plaintiffs' improper statement does not help Plaintiffs' cause in this instance, and Aurobindo has not filed a motion to strike. Aurobindo nonetheless raises the issue for the Court in case the Court might be inclined to strike the statement *sua sponte* as a reasonable sanction for Plaintiffs' blatantly disregarding Rules 7.1.2(a) and 7.1.3(a)(4).

[2] Unless otherwise noted, citations to Exhibits to the Barry Declaration refer to the Exhibits to the Declaration of George J. Barry III submitted in support of Aurobindo's Motion. (*See* D.I. 224.)

underscore the Asserted Claims' failure to transform the natural phenomenon embodied in the Asserted Claims into patentable subject matter. Plaintiffs make much of the fact that the Asserted Claims identify specific mutations amenable to migalastat, but this rings hollow as significant in view of the '011 patent's claims directed to the very same method of treating Fabry disease "in a patient in need thereof." Plaintiffs do not dispute that only patients with amenable mutations need migalastat.

Nor can Plaintiffs seriously contend that treating Fabry Disease patients with 150 mg of migalastat hydrochloride (equivalent to 123 mg of migalastat base) every other day was not well-understood as of the earliest possible priority date for the Asserted Claims, May 30, 2017 (*See* D.I. 226 at 5-8 (detailing Asserted Patents and Claims)). Indeed, the patent application that led to issuance of Plaintiffs' '011 patent, which describes and claims administration of 150 mg of migalastat every other day (*see* Ex. 5 at 24:17-18 and claim 1), was published five years earlier, in 2012. (*See* Ex. 5 at 1 "Prior Publication Data."). This does not raise a question as to what is disclosed in the prior art. It answers the question of what precisely do the Asserted Claims claim that the '011 patent claims do not? Answer: Nothing. Adding a reference to the specific genetic mutation does not in any way alter the claimed method of treatment.

The best argument Plaintiffs can make is that treating patients known to have ***the*** specific mutations claimed in the Asserted Claims with Migalastat was not known before those mutations were determined to be amenable to migalastat. But, that argument must fail in view of the fact that whether a mutation is amenable to migalastat treatment is a question answered by nature through the use of a diagnostic tool not claimed in the Asserted Claims to evaluate a mutation's natural response to migalastat. That, Aurobindo submits, is an accurate summary of the test results embodied in the construction of the term "HEK Assay Amenable Mutation" to which the Parties

have agreed. (*See* D.I. 226 at 6 n.3). Plaintiffs' contention that Aurobindo has not squarely addressed these issues in its opening brief is completely unfounded. (*See* D.I. 226 at 10-13 analyzing and applying the *Alice* framework in the context of the on-point *Mayo* decision preceding it.) To be clear, there is nothing in the Asserted Claims that transforms the unpatentable natural phenomenon of migalastat amenability into a patentable invention.

The key question before the Court is not whether Plaintiffs are reclaiming prior art (they are) but whether Plaintiffs have improperly extended their '011 patent monopoly with patent claims directed to alleged inventions that are distinguishable from Plaintiffs' other alleged inventions only on the basis of the results of a diagnostic documentation of natural phenomenon. Perhaps an even better focus is on whether Plaintiffs are entitled to what is effectively a patent grant in perpetuity until the end of time covering the claimed method to treat Fabry Disease for each new mutation identified as amenable. Aurobindo respectfully submits that this is the absurdity that would result from upholding the Asserted Claims as patentable under § 101. One could easily extend that absurdity further: Plaintiffs' logic would support patent claims for treatment methods directed individual diagnoses for every disease imaginable. Each new patient that qualifies for a claimed method of treatment, as determined by an unclaimed diagnostic method, would present a unique class of entities giving rise to a new patent monopoly specific to the individualized diagnosis and the entity class's shared traits. The slippery slope need not be so steep to find cause to reject Plaintiffs' positions, however.

The *Two-Way Media* case cited by Plaintiffs is instructive. (*See* D.I. 230 at 16.) While Plaintiffs point to *Two-Way Media* to (wrongly) suggest that Aurobindo has confused novelty with patentability, in actuality *Two-Way Media* further underscores the flaws in Plaintiffs' arguments. *See generally, Two-Way Media Ltd. v. Comcast Cable Communs., LLC*, 874 F.3d 1329 (Fed. Cir.

2017). The claims at issue in *Two-Way Media* embodied multi-step methods for transmitting and/or metering certain information. Similar to the Plaintiffs in this case, the patent defender in *Two-Way Media* interpreted the asserted claims to be "directed to computer architecture that solved . . . technical problem," but the district court concluded that "[n]one of the claims . . . recite or refer to anything that could be described as an architecture." *Id.* at 1336. The Federal Circuit agreed and concluded that, while the patent specification described an architecture, the claims themselves did not and, thus, were "missing an inventive concept." *Id.* at 1338. "Nothing in the claims or their constructions, including the use of 'intermediate computers,' requires anything other than conventional computer and network components operating according to their ordinary functions." *Id.* at 1339. Clearly, the Federal Circuit's understanding of what constitutes "conventional computer and network components" was informed by prior art technology, and *Two-Way Media* simply does not preclude pointing to prior art as Aurobindo has done to illustrate lack of an inventive concept. *See also Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 221-22 (2014) (addressing patentability and favorably describing the earlier *Mayo* decision's comparison between what was claimed and was known before the claimed inventions and further describing *Mayo* as having determined that the inventions at issue "amounted to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients"); *Mayo Collaborative Svcs. v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 79 (2012) (evaluating patentability and noting, "methods for determining metabolite levels were well known in the art" and, thus, the asserted claims merely told "doctors to engage in well understood, routine, conventional activity previously engaged in by scientists who work in the field"); *BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1340, 1350 (Fed. Cir. 2016) (finding patentability after comparing what was claimed with what was known, noting, "Filtering content

on the Internet was already a known concept, and the patent describes how its particular arrangement of elements is a technical improvement over prior art ways of filtering such content"); *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1319-21 (Fed. Cir. 2016) (comparing what was claimed with what was known in the course of invalidating a patent under § 101).[3]

That is precisely the case here, where Plaintiffs point to an assay described in the patent specifications as the source of an inventive concept but cannot point to anything in the Asserted Claims themselves claiming the described assay or requiring performance of the described assay. The fact that Aurobindo points to the Plaintiffs' own '011 patent to illustrate the lack of an inventive step does not convert Aurobindo's focus from patentability to novelty.

Aurobindo respectfully submits the *Mayo*, *Myriad, Athena Diagnostics* and *Genetic Techs. Ltd.* cases all support Aurobindo's argument that the Asserted Claims are directed to a natural phenomenon and squarely support granting Aurobindo's motion for the reasons set forth in its opening brief. (*See* D.I. 226 at 10-13.) Plaintiffs make no serious attempt to distinguish any of these cases in their response.

[3] The issue of novelty was summarily addressed by the *Two-Way Media* decision, and Plaintiffs offer no analysis supporting their conclusory assertion that Aurobindo is making a novelty argument. Notably, the *Two-Way Media* decision's novelty discussion was grounded in the district court's choice not to permit the patent ***defender*** to survive a § 101 challenge based on extrinsic evidence the patent ***defender*** contended demonstrated "the purported technical innovations of its invention." *Two-Way Media Ltd.*, 874 F.3d at 1339-40. Similarly here, Plaintiffs attempt to survive Aurobindo's challenge by pointing to extrinsic evidence pertaining to the assay described in the Asserted Patents' specifications (but not claimed in the Asserted Claims) as the relevant technical innovation. Therefore, it is Plaintiffs who are committing the sin of converting Aurobindo's § 101 challenge into a novelty issue. Aurobindo respectfully submits that *Two-Way Media* precludes Plaintiffs from relying on unclaimed assays to demonstrate the patentability of the Asserted Claims, and Plaintiffs' accusation against Aurobindo regarding novelty is entirely unfounded.

Furthermore, the cases on which Plaintiffs rely are readily distinguishable on the facts. As Plaintiffs acknowledge, the *Vanda* court addressed claims directed to "performing a genetic test to determine whether a patient has a specific genotype and (ii) depending on the results of the genetic test, administering either less than 12 mg/day of iloperidone or between 12 mg/day and 24 mg/day." (D.I. 230 at 10.) Thus, the claims in *Vanda* were directed to a ***claimed*** diagnostic test that informed prescribers as to the appropriate dosage. *See id.*; *see also Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 at 1121 (Fed. Cir. 2018) (detailing representative claim). Likewise, regarding the Federal Circuit's *Endo* decision, Plaintiffs acknowledge the decision concerned patent claims requiring "first testing the level of renal impairment through an assay measuring the creatine clearance rate …." (D.I. 230 at 11.) *See Endo Pharms. Inc. v. Teva Pharms. USA, Inc.*, 919 F.3d 1347, 1350-51 (Fed. Cir. 2019) (describing representative claim). The Asserted Claims do not claim any test or assay or method for making any determination whatsoever. They claim methods of treating Fabry Patients amenable to migalastat whose Fabry mutation has been identified as migalastat amenable through the use of an unclaimed assay that analyzes migalastat's natural effect on Fabry mutations. Thus, *Vanda* and *Endo* are inapposite here.

The *Natural Alternatives* decision Plaintiffs discuss is even further afield. There the Federal Circuit addressed the district court's error in conflating the therapeutic effect of a method of treatment with an unpatentable natural phenomenon. *See generally Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019). *Natural Alternatives* might have relevance if Aurobindo was arguing that the methods of treatment claimed in the Asserted Claims are not patentable because the therapeutic effect of 150 mg of migalastat every other day is a natural phenomenon. That clearly is not Aurobindo's position. Aurobindo's position is that a Fabry mutation's amenability to migalastat is a natural phenomenon documented through the use

of an assay that is not claimed in the Asserted Claims, and there is nothing in the Asserted Claims that transforms that observation of amenability into a patentable invention.

Therefore, Aurobindo respectfully submits Plaintiffs have failed to raise a triable question as to whether the Asserted Claims are directed to a patent ineligible concept. They are. They reclaim a method of treatment distinguishable only by reference to the results of an unclaimed assay that documents the natural phenomenon of migalastat amenability. Moreover, as discussed further, the claims do not transform that concept into a patentable invention.

III. Plaintiffs Have Failed to Raise a Triable Question as to Whether the Asserted Claims Transform the Observation of Migalastat Amenability into a Patentable Invention.

As previewed, Plaintiffs' argument that the Asserted Claims transform migalastat amenability assay results into a patentable invention rests entirely on the alleged technical innovation of the assay itself. Plaintiffs' error is captured nicely in this excerpt from their responsive brief:

> Further, Amicus submitted voluminous material facts in expert discovery—that Aurobindo failed to rebut and ignores entirely in its motion—that would defeat summary judgment under *Alice* step two to the extent not resolved on step one. It was "not well-understood, routine, or conventional to be able to accurately identify which Fabry patients would be treatable with migalastat by the priority date … .

(D.I. 230 at 18.)

Thus, all Plaintiffs can and do point to as providing an inventive concept is extrinsic evidence pertaining to an unclaimed assay they say rocked the Fabry Disease world. In accordance with the *Two-Way Media* decision discussed above, that assay (which in reality reflects a tweak to a previously patented assay, as Aurobindo will demonstrate at trial if needed) cannot save the Asserted Claims because the Asserted Claims do not claim the assay or any sort of patient

screening step whatsoever. Aurobindo denies that it has ignored any so-called evidence Plaintiffs have proffered in this case. On the contrary, Aurobindo has determined that the so-called evidence Plaintiffs invoke (without any analysis that could aid the Court in its consideration of these issues) is not material to the issues raised by Aurobindo's motion, namely the scope and meaning of the plain language of the Asserted Claims and whether that plain language describes a patentable invention. For all of the reasons set forth in Aurobindo's opening brief and as further set out in this Reply, Aurobindo respectfully submits it does not, and the Asserted Claims must, therefore, fail under § 101.

IV. Conclusion

The Asserted Claims do no more than re-claim a previously patented method of treatment without adding any inventive concept. The Asserted Claims are distinguishable from what was known and understood about treating Fabry Disease with migalastat only by identifying specific Fabry mutations observed as amenable using an assay that is not claimed in the Asserted Patents and that does no more than document the natural phenomenon of migalastat amenability of a particular genetic mutation. Therefore, Aurobindo respectfully submits that the Asserted Patents cannot withstand scrutiny under the governing precedent, namely the *Alice, Mayo*, *Myriad, Athena Diagnostics* and *Genetic Techs. Ltd.* cases cited and discussed in Aurobindo's opening brief. Aurobindo, thus, requests that its motion for summary judgment be granted and judgment be entered in Aurobindo's favor on all claims.

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Respectfully submitted,

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